

# **EXHIBIT 16**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.	)	
a Massachusetts Corporation	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 04-12457 PBS
	)	
Arthrex, Inc.	)	
a Delaware Corporation, <i>et al.</i>	)	
	)	
Defendants.	)	
	)	

**DEFENDANTS' OPPOSITION TO DEPUY MITEK'S MOTION TO STRIKE  
ARTHREX'S RELIANCE ON ITS OWN INTERROGATORY CONTENTIONS AND  
DR. MUKHERJEE'S TIGERWIRE OPINIONS IN OPPOSITION TO DEPUY MITEK'S  
MOTION FOR SUMMARY JUDGMENT OF INFRINGEMENT AND NO  
INEQUITABLE CONDUCT**

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Charles W. Saber  
Stephen A. Soffen  
Salvatore P. Tamburo  
DICKSTEIN SHAPIRO LLP  
1825 Eye Street, N.W.  
Washington, D.C. 20006-5403  
Telephone: (202) 420-3116  
Facsimile: (202) 420-2201

Christopher Weld, Jr. (BBO # 522230)  
Raymond P. Ausrotas (BBO # 640315)  
TODD & WELD LLP  
28 State Street, 31st Floor  
Boston, MA 02109  
Telephone: (617) 720-2626  
Facsimile: (617) 227-5777

Counsel for Defendants  
Arthrex, Inc. and Pearsalls Ltd.

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## I. INTRODUCTION

Defendants Arthrex, Inc. (“Arthrex”) and Pearsalls, Ltd. (“Pearsalls”) (together, “defendants”) submit this Opposition to DePuy Mitek’s Motion to Strike Arthrex’s Reliance on its Own Interrogatory Contentions and Dr. Mukherjee’s TigerWire Opinions in Opposition to DePuy Mitek’s Motion for Summary Judgment of Infringement and No Inequitable Conduct (“Mitek Mot. to Str.”). For the reasons described hereinbelow, DePuy Mitek’s motion should be denied.

## II. DEPUY MITEK FAILED TO COMPLY WITH LOCAL RULE 7.1(a)(2), AND THEREFORE, ITS MOTION SHOULD BE STRICKEN

Local Rule 7.1(a)(2) of the U.S. District Court for the District of Massachusetts requires that “[n]o motion shall be filed unless counsel certify that they have conferred and have attempted in good faith to resolve or narrow the issue.” In what has become a rather disturbing trend, for the second time in as many motion filings, DePuy Mitek made no attempt to comply with this local rule before filing its motion.

Just as was the case with the last motion filed by DePuy Mitek, prior to being served with the motion, defendants had no idea that DePuy Mitek objected to defendants’ citation of their interrogatory responses in their Opposition to DePuy Mitek’s Motion for Summary Judgment, or that DePuy Mitek objected to Dr. Mukherjee’s opinions related to TigerWire. Here again, had DePuy Mitek made *any* effort to comply with the local rules, defendants would have had the opportunity to explain why their interrogatory responses were used for non-hearsay purposes and why Dr. Mukerjee’s opinions on TigerWire are admissible. However, since DePuy Mitek did not contact defendants regarding its objections, this Court is once again forced to address the entirety of DePuy Mitek motion.

A. DePuy Mitek's Motion is Another Transparent Attempt to Circumvent The Page Limit Set Forth in Local Rule 7.1(b)(4)

Just as transparent as its last motion, this DePuy Mitek motion has all the trappings of an attempt to circumvent the Court's page limit. The issues raised by this motion could have, and should have, been raised in DePuy Mitek's Reply to its Summary Judgment Motion. The combined pages of this motion and the Reply was 26 pages, well in excess of the page limitation for motion papers. By filing a separate motion instead of including these arguments in its Reply, DePuy Mitek was able to extend the page limit of the Reply without seeking the defendants' consent or the permission of the Court. DePuy Mitek has now used this tactic twice and it should not be tolerated. On this basis alone, DePuy Mitek's motion should be denied without leave to refile.

**III. SHOULD THE COURT CONSIDER DEPUY MITEK'S MOTION ON THE MERITS, THE MOTION SHOULD STILL BE DENIED**

A. Defendants' Citation to Their Interrogatory Responses Was For Non-Hearsay Purposes

In an error that should prove to be fatal to its summary judgment motion for infringement, DePuy Mitek ignored two defenses raised by defendants in their interrogatory responses – *i.e.*, that the ends of FiberWire suture are tipped, thereby restricting the fiber mobility of the two dissimilar materials and the reverse doctrine of equivalents. As defendants explained in their summary judgment opposition, DePuy Mitek's omission of any arguments addressing these two defenses should be fatal to DePuy Mitek's summary judgment motion since it has effectively waived those arguments. Defendants' Opposition to DePuy Mitek's Motion for Summary Judgment of Infringement and No Inequitable Conduct ("Def's SJ Opp.") at 8-9. To find otherwise would be unfair to defendants since they do not have an opportunity to respond to DePuy Mitek's new arguments, raised for the first time in its reply. *See, e.g., Novosteel SA v. United States*, 284 F.3d 1261, 1273-74 (Fed. Cir. 2002) (holding "as a matter of litigation

fairness and procedure” arguments that did not appear in movant’s original summary judgment motion but did appear in movant’s reply brief were waived).

With regard to defendants’ identification of their two defenses, DePuy Mitek asserts that “Arthrex’s reliance on its contention interrogatory responses should be stricken,” since these responses are “not admissible by Arthrex because they are hearsay.” Mitek Mot. to Str. at 1. DePuy Mitek apparently misunderstands the reasons that defendants cited to the interrogatory answers. Defendants plainly did not offer their interrogatory responses for the truth of the matter asserted, but rather, the purpose was to alert the Court to the fact that there are two non-infringement defenses of which DePuy Mitek was aware (because they were raised in the interrogatory answers), but chose to ignore in its summary judgment motion. Such use is *not* hearsay because the interrogatory answers are not offered for the truth of the matter asserted. 2 MCCORMICK ON EVID. §§ 249, 295 (6th ed.).

1. Tipping materially affects FiberWire’s handleability

Apparently, DePuy Mitek is trying to create a world where it can neglect to raise appropriate issues in its motion, present evidence in a Reply only after its neglect is called to its attention, and then contend that defendants should not be permitted to file a substantive response. Even if the Court were to rule that DePuy Mitek’s failure to raise these issues in its original summary judgment motion was not a waiver, surely fairness demands that defendants be permitted to respond. *See, e.g., Cia. Petrolera Caribe, Inc. v. Arco Caribbean, Inc.*, 754 F.2d 404, 410 (1st Cir. 1985).

DePuy Mitek engages in such gamesmanship because it knows full-well that multiple witnesses in this case -- including witnesses for both Arthrex and DePuy Mitek -- have testified that the ends of suture are tipped in order to stiffen the ends so as to facilitate attachment to instruments, including needles, and/or to insert the suture through tissue -- all handleability

purposes. This was the testimony of Kevin Grief, Shelby Cook, Ilya Koyfman and Gary McAlister. Ex. 1 at 53:23-54:2; Ex. 2 at 119:24-120:10; Ex. 3 at 106:5-10; Ex. 4 at 53:24-54:6. Thus, to the extent DePuy Mitek is not found to have waived its argument with regard to tipping -- as it rightfully should be -- the testimony of these several witnesses creates an issue of fact and DePuy Mitek's motion for summary judgment of infringement should be denied.<sup>1</sup>

2. The Reverse Doctrine of Equivalents applies because FiberWire operates in a manner opposite to that of the '446 patent

As DePuy Mitek is also well aware, Dr. Mukherjee stated that the '446 patent specification describes that the first fiber-forming material is a lubricious material, and that the second fiber-forming material is added for strength. Ex. 5 at 7. Dr. Mukerjee also stated that the fact that the first fiber-forming materials are lubricious but too weak for most suture applications is further made clear by the specification which states that "a volume fraction [of lubricating yarns] above about 80% may adversely affect the overall strength of the braid." *Id.* He also noted that "there is a tradeoff between the properties of the two materials -- one being lubricious but weak, the other being added for strength," and that "the specification further recognizes that gains in handleability/pliability outweigh and loss of strength." *Id.* Likewise, Dr. Mukherjee stated that, in 1992, UHMWPE -- as used in FiberWire -- was a well-known, highly specialized fiber material with strength properties that are far superior to those of general purpose PE. Ex. 6

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<sup>1</sup> DePuy Mitek also asserts that it is irrelevant whether FiberWire's ends infringe as long as the remainder of the suture infringes and cites two cases. Mitek's Reply in Support of its Motion for Summary Judgment of Infringement and No Inequitable Conduct ("Mitek's SJ Reply") at 4-5. Those cases, however, are inapposite since they address "comprising" claims and not "consisting essentially of" claims. It is well-known that one can not avoid infringement of a "comprising" claim simply by adding additional materials to the accused infringing product. The facts of this case are entirely different, however, since the transitional phrase is not "comprising," but "consisting essentially of." Thus, the question is not simply whether an unlisted ingredient has been added to an otherwise infringing product, but rather, whether the addition of that unlisted ingredient materially affects the handleability of the suture (*e.g.*, facilitating its insertion into needles, tissue, etc.). As demonstrated above, the adhesive does have such a material affect on the suture.



at 22. Further, as Dr. Brookstein acknowledged, UHMWPE is added to FiberWire for its strength, whereas PET is added for its flexibility. Ex. 7 at ¶ 56.

Having found this disclosure in the ‘446 patent, and with this explanation of the purposes of the materials used to make FiberWire, Dr. Mukherjee opined that “[t]he specification of the ‘446 patent describes that the first fiber-forming materials are added to improve suture handleability and that such materials are too weak for most suture applications. It is the second fiber-forming materials that are added for increased strength. The way in which the individual materials act in FiberWire is the opposite. UHMWPE that is added for strength and the PET is added to improve knot tying – a well-known handleability characteristic.” Ex. 5 at 18. This testimony establishes a defense under the reverse doctrine of equivalents. Thus, to the extent DePuy Mitek is not found to have waived its argument with regard to the reverse doctrine of equivalents -- as it rightfully should be -- Dr. Mukherjee’s statements create an issue of fact and DePuy Mitek’s motion for summary judgment of infringement should be denied.<sup>2</sup>

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<sup>2</sup> DePuy Mitek stated that “it is not clear whether the reverse doctrine of equivalents is even a viable defense.” Mitek’s SJ Reply at 1. The Federal Circuit, however, has confirmed that it is a viable defense. For example, in *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1351 (Fed. Cir. 2003), although the facts did not support a finding of reverse doctrine of equivalents, the Federal Circuit endorsed it as a viable defense and cited the Supreme Court in *Graver Tank & Mfg. Co. v. Linde Air Prod. Co.* 339 U.S. 605, 608-09 (1950), cited Donald S. Chisum, 5A CHISUM ON PATENTS § 18.04 (1999), and also cited two other Federal Circuit opinions (*Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d. 1565, 1581 (Fed. Cir. 1991), and *Del Mar Avionics, Inc. v. Quinton Instr. Co.*, 836 F.2d. 1320, 1325 (Fed. Cir. 1987)).

Since *Amgen*, Judge Posner (N.D.Ill.) also recognized the doctrine of equivalents as a viable defense in *Smithkline Beecham Corp. v. Apotex Corp.*, 247 F.Supp.2d 1011, 1044-45 (N.D.Ill. March 3, 2003). He cited the Federal Circuit decision in *Amgen* and stated that the present case was a good case for the reverse doctrine of equivalents defense but since the defendant did not invoke it, he could not rely on it.

B. DePuy Mitek Cannot Strike the Additional Evidence That Shows That the Addition of Nylon to FiberWire Materially Affects the Basic and Novel Characteristics of the Claimed Invention

DePuy Mitek has apparently taken the position that since Dr. Mukherjee could not recall at his deposition every detail of every suture he evaluated in connection with this case, then that means Dr. Mukherjee did not review any sutures. Mitek Mot. to Str. at 4-5. That, of course, is not the law. A deposition is not a memory test, nor should it be treated as one. Dr. Mukherjee stated in his Responsive Expert Report that he “held a sample of both commercial FiberWire and TigerWire and the TigerWire felt stiffer and more coarse than the same sized FiberWire.” Ex. 5 at 30-31. Dr. Mukherjee also opined that “the coarse feel [of TigerWire] would suggest that the addition of the nylon would adversely affect knot tie-down.” Ex. 5 at 31. Dr. Mukherjee spent decades working in the suture industry and is highly qualified to opine on whether one suture feels stiffer and more coarse than another suture and what affect, if any, such coarseness would have on knot tie-down.

Unwilling to address this evidence head-on, DePuy Mitek’s tactic was to subject Dr. Mukherjee to a memory test at his deposition. The fact that Dr. Mukherjee did not recall every detail of every test he conducted while sitting for his deposition is unremarkable. What is notable, however, is the fact that DePuy Mitek intentionally did not ask Dr. Mukherjee about the specific statements he made in his expert report regarding his test of the stiffness and coarseness of TigerWire compared with FiberWire -- even after Dr. Mukherjee referred DePuy Mitek to his report where he says that nylon does affect pliability. Ex. 8 at 526:4-13. Rather, DePuy Mitek simply concludes, with a wave of the hand, that the tests were not conducted because Dr. Mukherjee did not remember every single test that he performed to support his opinions. Try as it may, DePuy Mitek can not sweep Dr. Mukherjee’s report under the rug in the hopes that it will disappear. Of course, Dr. Mukherjee conducted his test and his opinions were as stated in his

report. DePuy Mitek does not challenge Dr. Mukherjee's test as unscientific, nor does it challenge Dr. Mukherjee's qualifications to render any such opinion. The only attack on Dr. Mukerjee's test is a baseless conclusory statement that he did not conduct it. As explained above, that is simply not true.

DePuy Mitek spends four pages attacking Dr. Mukherjee's "drape" test as unscientific. Mitek Mot. to Str. at 5-8. But Dr. Mukherjee readily acknowledged that the drape test was not scientific and that his opinions in this case were not based solely on the drape test. Rather, the drape test was consistent with Dr. Mukerjee's other tests and merely served to confirm his opinions regarding TigerWire's pliability.

C. In Any Event, TigerWire Does Not Infringe for the Same Reasons That FiberWire Does Not Infringe

It is important to note that the addition of nylon to TigerWire simply provides defenses beyond those available for FiberWire. The infringement defenses applicable to FiberWire apply equally to TigerWire. Like FiberWire, TigerWire is also made of UHMWPE and PET (with nylon as a substitute for one of the PET filaments). Thus, TigerWire does not infringe because UHMWPE is not "PE" within the meaning of the '446 patent.

Similarly, TigerWire, just like FiberWire, is coated and the addition of the coating materially affects the basic and novel characteristics of the claimed invention. DePuy Mitek can not create a genuine issue of material fact on TigerWire by pointing to the testimony of Dr. Brookstein or Dr. Burks. Dr. Brookstein did no tests on TigerWire coating. Moreover, even if his 4.8% coating measurement<sup>3</sup> on FiberWire applied to TigerWire, there is absolutely no

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<sup>3</sup> Defendants note that in their Reply Memorandum in Support of their Motion for Summary Judgment ("Def's Reply SJ Br."), they inadvertently misstated Dr. Brookstein's coating measurement. Instead of 3.4% coating by weight, Dr. Brookstein actually measured even more of a coating content on FiberWire -- 4.8% coating by weight.

support for Dr. Brookstein's opinion that 4.8% is a "very small amount of coating." In fact, all the evidence is to the contrary. *See* Def's Reply SJ Br. at 13-14.

Likewise, Dr. Burks' testimony can not create a genuine issue of fact. First, he did no tests on TigerWire. Second, his assertion (with respect to FiberWire) that differences were "subtle" has nothing to do with how FiberWire (or TigerWire) is used in a surgical environment. For his report, Dr. Burks tested FiberWire both "dry" and "wet." He explained that "wet" is how FiberWire is used in a surgical environment (Ex. 9 at ¶ 7) and that, with respect to all of his tests, "the difference between the two samples *was even more pronounced* when they were wet, which is how I am accustomed to using FiberWire." Ex. 9 at ¶¶ 11, 12. [Emphasis added.] Dr. Burks' comments about a subtle difference related *only* to "dry" FiberWire. Ex. 10 at 87:7-13.<sup>4</sup> Notably, at his deposition, Dr. Burks was *not* asked a single question about his opinions on wet FiberWire, which is how it is used in the surgical environment. All of DePuy Mitek's questions were directed to his opinions on "dry" FiberWire. Thus, Dr. Burks' opinion that the differences were "more pronounced" when wet, as the product is actually used, remains unrebutted. As defendants previously stated, if the affect of the unlisted material is of importance or of consequence to those of ordinary skill in the art -- here Dr. Burks believes there is a "pronounced" difference -- it is a "material" affect. *PPG Indus. v. Guardian Indus. Corp.* 156 F.3d 1351, 1354 (Fed. Cir. 1998).

#### IV. CONCLUSION

For all the foregoing reasons, DePuy Mitek's motion should be denied.

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<sup>4</sup> At his deposition, Dr. Burks was only asked to perform tests on "dry" FiberWire, where the differences are less pronounced. Even here, he got the answer correct each time.

Dated: October 4, 2006

Respectfully submitted,

By: /s/Charles W. Saber  
Charles W. Saber  
Stephen A. Soffen  
Salvatore P. Tamburo  
DICKSTEIN SHAPIRO LLP  
1825 Eye Street, N.W.  
Washington, D.C. 20006-5403  
Telephone: (202) 420-3116  
Facsimile: (202) 420-2201  
Christopher Weld, Jr. (BBO # 522230)  
Raymond P. Ausrotas (BBO # 640315)  
TODD & WELD LLP  
28 State Street, 31st Floor  
Boston, MA 02109  
Telephone: (617) 720-2626  
Facsimile: (617) 227-5777  
Counsel for Defendants  
Arthrex, Inc. and Pearsalls Ltd.

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that a true and correct copy of the foregoing DEFENDANTS' OPPOSITION TO DEPUY MITEK'S MOTION TO STRIKE ARTHREX'S RELIANCE ON ITS OWN INTERROGATORY CONTENTIONS AND DR. MUKHERJEE'S TIGERWIRE OPINIONS IN OPPOSITION TO DEPUY MITEK'S MOTION FOR SUMMARY JUDGMENT OF INFRINGEMENT AND NO INEQUITABLE CONDUCT was served, via the Court's email notification system on the following counsel for Plaintiff on the 4th day of October 2006:

Lynn A. Malinoski  
Woodcock Washburn, LLP  
One Liberty Place, 46th Floor  
Philadelphia, PA. 19103  
Telephone: (215) 568-3100  
Facsimile: (215) 568-3439

Daniel J. Gleason  
Nutter McClennan & Fish LLP  
World Trade Center West  
155 Seaport Boulevard  
Boston, MA 02210-2604  
Telephone: (617) 439-2000  
Facsimile: (617) 310-9000

\_\_\_\_\_  
/s/Charles W. Saber